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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,138	06/12/2001	James J. Hickman	18805-81106	5733

7590

02/11/2003

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,138

Applicant(s)

HICKMAN ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to a biosensor comprising: a substrate in contact with a culture medium; a cell network composed of at least one electrically excitable cell; and a signal transducer classified in class 435, subclass 347.
- II. Claims 19-22, drawn to a biosensor comprising: a substrate; first and second neurons; and a first and second transducer, classified in class 435, subclass 347.
- III. Claims 23 and 24, drawn to a method of detecting a bioeffecting substance in a test sample comprising: providing a biosensor; contacting the test sample with the biosensor; monitoring the transducer; and correlating the signal to the presence or absence of the bioeffecting substance, classified in class 435, subclass 29.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (i.e. the biosensor further comprising a culture medium) does not require the particulars of the subcombination as claimed because the biosensor of Group I can comprise any electrically excitable cell, not just the neuronal cell of Group II. The

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subcombination has utility by itself because the subcombination as claimed comprises all of the requisite components of a functional biosensor according to the invention.

Inventions I and II are related to Invention III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced using either of the patentably distinct products of Groups I or II, or with other product capable of detecting a bioeffecting substance such as a patch clamped cell or a cell loaded with a tracer molecule that is modified (e.g. a calcium dye) or mobilized (e.g. radioisotopes) in response to a bioeffecting substance.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct Inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: (a) the biosensor of Group I, wherein the insulating and/or barrier layer is selected from silica, silicon, germanium, gallium, arsenide, epoxy resin, polystyrene, polysulfone, aluminum, aluminum, platinum, alumina, silicone, fluoropolymers, polyesters, acrylic copolymers, polygalactin, and polylactates; (b) the biosensor of Group I, wherein the cell adhesion promoter is selected from the group consisting of adhesion promoters containing a

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terminal group consisting of $\text{-NHCH}_2\text{CH}_2\text{NHCH}_2\text{CH}_2\text{NH}_2$, $\text{-NHCH}_2\text{CH}_2\text{NH}_2$, 11-aminoundecyl, 3-aminopropyl, 3-(1-aminopropoxy)-3, 3-dimethyl-1-propenyl, 6-(aminohexyl)propyl, N-(2-aminethyl)-3-aminopropyl, $\text{-(CH}_2\text{)}_3\text{-NH-(CH}_2\text{)}_3$, Gly-Arg-Gly-Asp-Tyr-, and Gly-Tyr-Ile-Gly-Ser-Arg-Tyr; and (c) the biosensor of Group I, wherein the cell adhesion promoter is selected from the group consisting of tridecafluoro-1,1,2,2-tetrahydrooctyl)-1-dimethylchlorosilane, tridecafluoro-1,1,2,2-tetrahydrooctyl)-1-trichlorosilane, tridecafluoro-1,1,2,2-tetrahydrooctyl)-1-methyldichlorosilane, tridecafluoro-1,1,2,2-tetrahydrooctyl)-1-triethoxysilane, (3,3,3-trifluoropropyl)trichlorosilane, (3,3,3-trifluoropropyl)methyldichlorosilane, (3,3,3-trifluoropropyl)dimethylchlorosilane, (3,3,3-trifluoropropyl)methyldimethoxysilane, (3,3,3-trifluoropropyl)trimethoxysilane, (heptafluoroisopropoxy)propylmethyldichlorosilane, (3-pentafluorophenylpropyl)dimethylchlorosilane, polyethylene glycols, silanes having a branched $\text{C}_3\text{-C}_{40}$ alkyl terminus, silanes having an unbranched $\text{C}_3\text{-C}_{40}$ terminus, phenyl groups, and inhibitory biological macromolecules.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of (a), (b) and (c) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 6 and 7 are generic to the species of (a); claims 1, 9 and 10 are generic to the species of (b); and claims 1, 9 and 11 are generic to the species of (c).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
February 5, 2003



**JAMES KETTER
PRIMARY EXAMINER**